

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Criticare Systems, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186-4054

Attn: *Mr. Emil Soika*  
*President and Chief Executive Officer*

Dear Mr. Soika:

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS") has reason to believe that Criticare Systems, Inc. ("Criticare"), has committed 20 violations of the Export Administration Regulations (the "Regulations"),<sup>1</sup> which are issued under the authority of the Export Administration Act of 1979 (the "Act").<sup>2</sup> Specifically, BIS charges that Criticare committed the following violations:

**Charges 1 - 10 (15 C.F.R. §764.2(a) - Engaging in Unauthorized Exports to Iran.)**

On ten occasions between on or about March 22, 1999 and on or about August 15, 2002, Criticare engaged in conduct prohibited by the Regulations by exporting medical equipment subject to the Regulations and the Iranian Transaction Regulations from the United States through the United Kingdom to Iran without the required U.S. Government authorization. Section 746.7 of the Regulations requires Office of Foreign Assets Control, U.S. Department of Treasury, ("OFAC") authorization for the

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<sup>1</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2004). The violations charged occurred from 1999 through 2002. The Regulations governing the violations at issue are found in the 1999 through 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1999-2002)). The 2004 Regulations establish the procedures that apply to this matter.

<sup>2</sup> 50 U.S.C. app. §§ 2401- 2420 (2000). From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized by Pub. L. No. 106-508 (114 Stat. 2360 (2000)) and it remained in effect through August 20, 2001. Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2003 (3 C.F.R., 2003 Comp., p. 328), continues the Regulations in effect under IEEPA. The Act and Regulations are available on the Government Printing Office website at: <http://w3.access.gpo.gov/bis/>.

export, from the United States to Iran, of items subject to the Regulations and the Iranian Transactions Regulations. OFAC did not authorize the export of the medical equipment. Therefore, Criticare committed ten violations of Section 764.2(a).

**Charges 11-20 (15 C.F.R. §764.2(a) - Failing to Submit Required Shipper's Export Declarations.)**

On ten occasions, between on or about March 22, 1999 and on or about August 15, 2002, Criticare engaged in conduct prohibited by the Regulations by failing to submit to the U.S. Government required Shipper's Export Declarations ("SED") for the export of medical equipment subject to the Regulations from the United States through the United Kingdom to Iran. Section 758.1 of the Regulations requires the filing of an SED with the U.S. Government for all exports of items subject to the Regulations that are destined for Iran. Therefore, Criticare committed ten violations of Section 764.2(a).

Accordingly, Criticare is hereby notified that an administrative proceeding is instituted against it pursuant to Section 13(c) of the Act and Part 766 of the Regulations for the purpose of obtaining an order imposing administrative sanctions, including any or all of the following:

The maximum civil penalty allowed by law of \$11,000 per violation;<sup>3</sup>

Denial of export privileges; and/or

Exclusion from practice before BIS.

If Criticare fails to answer the charges contained in this letter within 30 days after being served with notice of issuance of this letter, that failure will be treated as a default. (Regulations, Sections 766.6 and 766.7). If Criticare defaults, the Administrative Law Judge may find the charges alleged in this letter to be true without hearing or further notice to Criticare. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty on each charge in this letter.

Criticare is further notified that it is entitled to an agency hearing on the record if it files a written demand for one with its answer. (Regulations, Section 766.6). Criticare is also entitled to be represented by counsel or other authorized representative who has power of attorney to represent it. (Regulations, Sections 766.3(a) and 766.4).

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<sup>3</sup> See 15 C.F.R. §6.4(a)(4) (2004).

Criticare Systems, Inc.  
Proposed Charging Letter  
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The Regulations provide for settlement without a hearing. (Regulations, Section 766.18). Should Criticare have a proposal to settle this case, Criticare or its representative should transmit the offer to the individual representing BIS named below.

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, Criticare's answer must be filed in accordance with the instructions in Section 766.5(a) of the Regulations with:

U.S. Coast Guard ALJ Docketing Center  
40 S. Gay Street  
Baltimore, Maryland 21202-4022

In addition, a copy of Criticare's answer must be served on BIS at the following address:

Chief Counsel for Industry and Security  
Attention: Charles Wall  
Room H-3839  
United States Department of Commerce  
14th Street and Constitution Avenue, N.W.  
Washington, D.C. 20230

Charles Wall is representing BIS in this case; any communications that you may wish to have concerning this matter should occur through him. He may be contacted by telephone at (202) 482-5301.

Sincerely,

Acting Director  
Office of Export Enforcement



WHEREAS, Criticare filed a voluntary self-disclosure with BIS's Office of Export Enforcement in accordance with Section 764.5 of the Regulations concerning the transactions at issue herein;

WHEREAS, BIS has notified Criticare of its intention to initiate an administrative proceeding against Criticare, pursuant to the Act and the Regulations;

WHEREAS, BIS has issued a proposed charging letter to Criticare that alleged that Criticare committed 20 violations of the Regulations, specifically:

1. *Ten Violations of 15 C.F.R. §764.2(a) - Engaging in Unauthorized Exports to Iran:*  
On ten occasions between on or about March 22, 1999 and on or about August 15, 2002, Criticare engaged in conduct prohibited by the Regulations by exporting medical equipment subject to the Regulations and the Iranian Transaction Regulations from the United States through the United Kingdom to Iran without the required U.S. Government authorization. Section 746.7 of the Regulations requires Office of Foreign Assets Control, U.S. Department of Treasury, ("OFAC") authorization for the export, from the United States to Iran, of items subject to the Regulations and the Iranian Transactions Regulations. OFAC did not authorize the export of the medical equipment.
2. *Ten Violations of 15 C.F.R. §764.2(a) - Failing to Submit Required Shipper's Export Declarations:* On ten occasions, between on or about March 22, 1999 and on or about August 15, 2002, Criticare engaged in conduct prohibited by the Regulations by failing to submit to the U.S. Government the required Shipper's

Export Declarations (“SED”) for the export of medical equipment subject to the Regulations from the United States through the United Kingdom to Iran. Section 758.1 of the Regulations requires the filing of an SED with the U.S. Government for all exports of items subject to the Regulations that are destined for Iran.

WHEREAS, Criticare has reviewed the proposed charging letter and is aware of the allegations made against it and the administrative sanctions which could be imposed against it if the allegations are found to be true;

WHEREAS, Criticare fully understands the terms of this Agreement and the Order (“Order”) that the Assistant Secretary of Commerce for Export Enforcement will issue if she approves this Agreement as the final resolution of this matter;

WHEREAS, Criticare enters into this Agreement voluntarily and with full knowledge of its rights;

WHEREAS, Criticare states that no promises or representations have been made to it other than the agreements and considerations herein expressed;

WHEREAS, Criticare neither admits nor denies the allegations contained in the proposed charging letter;

WHEREAS, Criticare wishes to settle and dispose of all matters alleged in the proposed charging letter by entering into this Agreement; and

WHEREAS, Criticare agrees to be bound by the Order, if entered;

NOW THEREFORE, the Parties hereby agree as follows:

1. BIS has jurisdiction over Criticare, under the Regulations, in connection with the matters alleged in the proposed charging letter.
2. The following sanction shall be imposed against Criticare in complete settlement of the violations of the Regulations relating to the transactions specifically detailed in the voluntary self-disclosure and the proposed charging letter:
  - a. Criticare shall be assessed a civil penalty in the amount of \$45,000, which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of the Order. Payment shall be made in the manner specified in the attached instructions.
  - b. The timely payment of the civil penalty agreed to in paragraph 2.a. is hereby made a condition to the granting, restoration, or continuing validity of any export license, License Exception, permission, or privilege granted, or to be granted, to Criticare. Failure to make timely payment of the civil penalty set forth above may result in the denial of all of Criticare's export or reexport privileges for a period of one year from the date of imposition of the penalty.
3. Subject to the approval of this Agreement pursuant to paragraph 8 hereof, Criticare hereby waives all rights to further procedural steps in this matter (except with respect to any alleged violations of this Agreement or the Order, if entered), including, without limitation, any right to: (a) an administrative hearing regarding the allegations in the proposed charging letter; (b) request a refund of any civil penalty paid pursuant to this Agreement and the Order, if entered; (c) request any relief from the Order, if entered, including without limitation relief from the terms of

a denial order under 15 C.F.R. § 764.3(a)(2); and (d) seek judicial review or otherwise contest the validity of this Agreement or the Order, if entered.

4. Upon entry of the Order and timely payment of the \$45,000 civil penalty, BIS will not initiate any further administrative proceeding against Criticare in connection with any violation of the Act or the Regulations arising out of the transactions specifically detailed in the voluntary self-disclosure and the proposed charging letter.

5. BIS will make the proposed charging letter, this Agreement, and the Order, if entered, available to the public.

6. This Agreement is for settlement purposes only. Therefore, if this Agreement is not accepted and the Order is not issued by the Assistant Secretary of Commerce for Export Enforcement pursuant to Section 766.18(a) of the Regulations, no Party may use this Agreement in any administrative or judicial proceeding and the Parties shall not be bound by the terms contained in this Agreement in any subsequent administrative or judicial proceeding.

7. No agreement, understanding, representation or interpretation not contained in this Agreement may be used to vary or otherwise affect the terms of this Agreement or the Order, if entered, nor shall this Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the United States Government with respect to the facts and circumstances addressed herein.

8. This Agreement shall become binding on the Parties only if the Assistant Secretary of Commerce for Export Enforcement approves it by entering the Order, which will have the same force and effect as a decision and order issued after a full administrative hearing on the record.

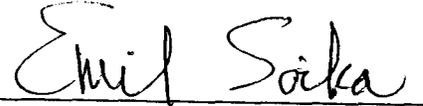
9. Each signatory affirms that he has authority to enter into this Settlement Agreement and to bind his respective party to the terms and conditions set forth herein.

BUREAU OF INDUSTRY AND SECURITY,  
U.S. DEPARTMENT OF COMMERCE



Acting Director  
Office of Export Enforcement

CRITICARE SYSTEMS, INC



Emil Soika  
President and Chief Executive Officer

Date: DEC 03 2004

Date: 12-1-04

UNITED STATES DEPARTMENT OF COMMERCE  
BUREAU OF INDUSTRY AND SECURITY  
WASHINGTON, D.C. 20230

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In the Matter of: )  
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Criticare Systems, Inc. )  
20925 Crossroads Circle )  
Waukesha, WI 53186-4054 )  
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Respondent. )  
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ORDER RELATING TO CRITICARE SYSTEMS, INC.

The Bureau of Industry and Security, U.S. Department of Commerce (“BIS”) has notified Criticare Systems, Inc. (“Criticare”) of its intention to initiate an administrative proceeding against Criticare pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2004)) (“Regulations”),<sup>1</sup> and Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”),<sup>2</sup> by issuing a proposed charging letter to Criticare that alleged that Criticare committed 20 violations of the Regulations. Specifically, the charges are:

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<sup>1</sup> The violations charged occurred between 1999 and 2002. The Regulations governing the violations at issue are found in the 1999 through 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1999-2002)). The 2004 Regulations set forth the procedures that apply to this matter.

<sup>2</sup> From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) (“IEEPA”). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004 (69 *Fed. Reg.* 48763, August 10, 2004), has continued the Regulations in effect under the IEEPA.

1. *Ten Violations of 15 C.F.R. §764.2(a) - Engaging in Unauthorized Exports to Iran:* On ten occasions between on or about March 22, 1999 and on or about August 15, 2002, Criticare engaged in conduct prohibited by the Regulations by exporting medical equipment subject to the Regulations and the Iranian Transaction Regulations from the United States through the United Kingdom to Iran without the required U.S. Government authorization. Section 746.7 of the Regulations requires Office of Foreign Assets Control, U.S. Department of Treasury, (“OFAC”) authorization for the export, from the United States to Iran, of items subject to the Regulations and the Iranian Transactions Regulations. OFAC did not authorize the export of the medical equipment.
2. *Ten Violations of 15 C.F.R. §764.2(a) - Failing to Submit Required Shipper’s Export Declarations:* On ten occasions, between on or about March 22, 1999 and on or about August 15, 2002, Criticare engaged in conduct prohibited by the Regulations by failing to submit to the U.S. Government the required Shipper’s Export Declarations (“SED”) for the export of medical equipment subject to the Regulations from the United States through the United Kingdom to Iran. Section 758.1 of the Regulations requires the filing of an SED with the U.S. Government for all exports of items subject to the Regulations that are destined for Iran.

WHEREAS, BIS and Criticare have entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein; and

WHEREAS I have approved of the terms of such Settlement Agreement;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of \$45,000 is assessed against Criticare, which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of this Order. Payment shall be made in the manner specified in the attached instructions.

SECOND, that, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C. §§ 3701-3720E (2000)), the civil penalty owed under this Order accrues interest as more fully described in the attached Notice, and, if payment is not made by the due date specified herein, Criticare will be assessed, in addition to the full amount of the civil penalty and interest, a penalty charge and an administrative charge, as more fully described in the attached Notice.

THIRD, that the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to Criticare. Accordingly, if Criticare should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of Criticare's export privileges for a period of one year from the date of entry of this Order.

FOURTH, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

This Order, which constitutes the final agency action in this matter, is effective immediately.



Julie L. Salcido  
Acting Deputy Assistant Secretary of  
Commerce for Export Enforcement

Entered this 7<sup>th</sup> day of December 2004.